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Registration Decision RD2013-10

Mono- and Di-Potassium Salts of Phosphorous Acid

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Registration Decision for Mono- and Di-Potassium Salts of Phosphorous Acid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Winfield Phosphite TGAI, Winfield Phosphite Colorless, Winfield Phosphite Extra, Winfield Phosphite Turf, and Confine Post, containing the active ingredient mono- and di-potassium salts of phosphorous acid, for the control of certain diseases on potatoes; fruiting vegetables; basil; brassica leafy vegetables; leafy vegetables; cucurbits; grapes; ginseng; strawberries; outdoor ornamentals; conifers and trees; and turf grasses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] PRD2012-25, *Proposed Registration Decision Mono- and Di-Potassium Salts of Phosphorous Acid*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for mono- and di-potassium salts of phosphorous acid and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-25. This decision is consistent with the proposed registration decision stated in PRD2012-25.

For more details on the information presented in this Registration Decision, please refer to PRD2012-25, *Proposed Registration Decision Mono- and Di-Potassium Salts of Phosphorous Acid*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Are Mono- and Di-Potassium Salts of Phosphorous Acid?

Mono- and di-potassium salts of phosphorous acid are fungicide active ingredients belonging to Group 33 as designated by the Fungicide Resistance Action Committee and are classified as phosphonates. The mode of action of phosphorous acid is both direct and indirect, and involves the induction of host plant resistance and the inhibition of oxidative phosphorylation. Mono- and di-potassium salts of phosphorous acid are the active ingredients contained in Winfield Phosphite TGAI, Winfield Phosphite Colorless, Winfield Phosphite Extra, Winfield Phosphite Turf and Confine Post.

Winfield Phosphite TGAI is based on the precedent technical grade active ingredient, mono- and di-potassium salts of phosphorous acid (Registration Number 29099). Confine Post is based on the precedent product Confine (Registration Number 29100) which is registered for suppression of late blight and pink rot on harvested potato tubers. The major new uses for Winfield Phosphite Colorless and Winfield Phosphite Extra are on potatoes; fruiting vegetables; basil; brassica leafy vegetables; leafy vegetables; cucurbits; grapes; ginseng; strawberries; outdoor ornamentals; conifers and trees and for Winfield Phosphite Turf use on grass turfs.

Health Considerations

Can Approved Uses of Uses of Mono- and Di-Potassium Salts of Phosphorous Acid Affect Human Health?

Mono- and di-potassium salts of phosphorous acid is unlikely to affect human health when used according to label directions.

Exposure to mono- and di-potassium salts of phosphorous acid may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Mono- and di-potassium salts of phosphorous acid are of low toxicity by the oral, dermal and inhalation routes, and minimally irritating to the eyes. The available information suggests that it is unlikely to have any short-term or prenatal developmental effects, as well as any significant genotoxic effects. The precautionary label statement—indicating that contact with skin, eyes, and

clothing must be avoided—and the personal protective equipment statement—that applicators and other handlers must wear a long-sleeved shirt, long pants, gloves, shoes plus socks, and protective eyewear—are effective mitigative measures to reduce the risk associated with the use of mono- and di-potassium salts of phosphorous acid.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary risk to humans is considered negligible based on a long history of use and the low toxicity of the end-use products. The available literature suggests that there is no toxicological concern from ingestion of the end-use product residues.

It is anticipated that the new uses of mono- and di-potassium salts of phosphorous acid in Canada on food crops will not pose a risk to any segment of the population including infants, children, adults and seniors, from consumption of produce from treated crops. In the United States, phosphorous acid has been designated Generally Regarded as Safe and the potassium salts of phosphoric acid have been exempted from the requirement of tolerance in and on all food commodities when used as an agricultural fungicide on food crops. The United States Environmental Protection Agency introduced an initiative whereby an exemption from the requirement of tolerance was established for ammonium, sodium, and potassium salts of phosphorous acid on all food commodities to permit post-harvest application to stored potatoes at 35 600 ppm or less of phosphorous acid.

No risk due to exposure from drinking water is anticipated as the end-use products are not to be applied near or directly to water and are likely to be degraded in the environment.

Occupational Risks From Handling End-use Products Containing Mono- and Di-Potassium Salts of Phosphorous Acid

Occupational exposure to individuals mixing, loading, or applying end-use products containing mono- and di-potassium salts of phosphorous acid is not expected to result in unacceptable risk when the end-use products are used according to label directions.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label are considered adequate to protect individuals from occupational exposure. Since the application is done by commercial applicators, exposure to bystanders is expected to be negligible.

Environmental Considerations

What Happens When Mono- and Di-Potassium Salts of Phosphorous Acid Are Introduced Into the Environment?

Mono- and di-potassium salts of phosphorous acid are not expected to pose a risk to the environment when used as a fungicide.

Mono- and di-potassium salts of phosphorous acid will enter the environment when used as a fungicide on field crops, ornamentals, turf, and potatoes in storage. Mono- and di-potassium salts of phosphorous acid produce phosphite ions when in contact with water. Over time, in soil, phosphite ions can be directly taken up by plant roots, slowly transform to phosphate (a plant nutrient), or bind with other substances in the soil. When phosphite ions get into lakes and rivers, it is expected that the phosphite will remain in the water phase. Phosphorous, in the form of phosphite, is not expected to be used by aquatic plants as a nutrient, but there is evidence that it could be used by certain kinds of bacteria. Mono- and di-potassium salts of phosphorous acid are not expected to accumulate in fish or other animals. It is also not expected that mono- and di-potassium salts of phosphorous acid will pose a risk to non-target terrestrial and aquatic species given its low toxicity to these organisms.

Value Considerations

What Is the Value of Winfield Phosphite Colorless, Winfield Phosphite Extra, Winfield Phosphite Turf, and Confine Post?

Winfield Phosphite Colorless, Winfield Phosphite Extra, Winfield Phosphite Turf and Confine Post are non-conventional fungicides with systemic properties that suppress major oomycete diseases, including downy mildews, on a wide range of crops. These products also pose a low risk of pest resistance development. These characteristics make them a valuable option for integration into spray programs.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Winfield Phosphite Colorless, Winfield Phosphite Extra, Winfield Phosphite Turf, and Confine Post to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because the technical product (Winfield Technical) containing mono- and di-potassium salts of phosphorous acid is used for formulating the commercial end-use products (Winfield Colorless, Winfield Extra, Winfield Turf, and Confine Post), the statement:

"Prevent access by unauthorized personnel" in the precaution section of the technical label will help mitigate the inappropriate use of the product, and help avoid accidental exposure. Other precautionary statements on the technical product and all end-use product labels, such as: "Avoid breathing vapors or spray mist, avoid contact with eyes, skin or clothing; remove contaminated clothing and wash clothing before use; applicators and/or other handlers must wear protective eyewear, long pants and long sleeved shirt, waterproof gloves, and shoes plus socks," should be effective in minimizing the potential for exposure.

Environment

No mitigative measures are required other than the standard precautionary label statements required for all commercial products.

Other Information

The relevant test data on which the decision is based (PRD2012-25, *Proposed Registration Decision Mono- and Di-Potassium Salts of Phosphorous Acid)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.